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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,147	09/22/2003	Shin Sadano	2003_0988A	5797

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER
DRODGE, JOSEPH W

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,147	SADANO ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15 and 17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16* is/are allowed.

6)☒ Claim(s) *15 and 17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Kumar patent 6,737,535. Kumar discloses marigold oleoresin product which has been purified by solvent extraction with a ketone or other solvent and by filtration techniques, contains a high level of lutein fatty acid ester content and may be in the form of a soft gelatin capsule and thus have a low viscosity (column 4, lines 50-63, column 5, lines 26-48 and column 5, line 65-column 6, line 2). The lutein content well exceeds the claimed 20 or 30 percent recited in claims 22 and 23 when purified (See Examples) and the disclosed conversion into soft gelatin capsule form inherently lowers the viscosity to below the claimed values.

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process as making. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re

Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). Also see *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324 and MPEP 2113.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar patent 6,737,535 in view of Sakato patent 5,288,550.

Kumar discloses marigold oleoresin product which has been purified by solvent extraction with a ketone or other solvent and by filtration techniques, contains a high level of lutein fatty acid ester content and may be in the form of a soft gelatin capsule and thus have a low viscosity (column 4, lines 50-63, column 5, lines 26-48 and column 5, line 65-column 6, line 2). The lutein content well exceeds the claimed 20 or 30 percent recited in claims 22 and 23 when purified (See Examples) and the disclosed conversion into soft gelatin capsule form inherently lowers the viscosity to below the claimed values.

The claims may optionally be deemed to differ in requiring the purified product to have a specific lowered viscosity. However, Sakato teaches that when pharmaceutical or health/vitamin supplement is dissolved in a hydrophilic solvent, such as acetone or other ketones and then enclosed in a soft gelatin capsule, the viscosity is lowered dramatically (especially column 1, lines 14-21, column 2, lines 26-42 and 57-68 and Table 3 of column 3). It would have been obvious to one of ordinary skill in the art to have modified the product of Kumar by lowering its velocity when converted into soft gelatin capsule form, as taught by Sakato, in order to make the product easier to swallow and digest. Particular viscosity values are shown in the Examples of Sakato.

When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process, the burden of proof is shifted to applicant to establish that their product is patentably distinct and not the examiner to show the same process as making. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re

Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). Also see *In re Brown*, 173 USPQ 685 and *In re Fessmann*, 180 USPQ 324 and MPEP 2113.

Claims 15, 17-22/15 and 27/15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madhavi et al patent 6,380,442 in view of Kanel et al of record, Rao et al PGPUBS Document US2004/0267033 and Kumar patent 6,737,535.

Madhavi et al disclose purification of marigold oleoresin (column 3, lines 5-11), optionally with a 1st step of solvent extraction with supercritical fluid (column 2, lines 38-42), and 2nd step of solvent extraction with an organic solvent (column 3, lines 14-16), 3rd step of cooling by freeze-drying together with precipitating (column 3, lines 54-61).

The claims firstly explicitly differ in requiring the oleoresin subjected to supercritical fluid extraction to result in an extraction residue, which is later further purified after separation from the extraction solution. However, Rao et al teach to subject marigold oleoresin to supercritical extraction so as to result in a purified extract which contains a lowered amount of undesirable odors, volatile substances and lower fatty oils (paragraphs 38 and 45). It would have been obvious to have conducted the Madhavi et al process by obtaining the resulting extract from the supercritical extraction step for further processing, as suggested in combination with Rao et al, to achieve a product of higher lutein extract content and lower amount of contaminants.

The claims secondly differ in requiring the organic solvent to be of the ketone family. Kanel et al teach solvent extraction of luteins and other carotenoids from plant material (column 5, lines 44-48 and Example 1a/column 9, lines 56 to column 10, line 4), by a multi-step solvent extraction process (especially column 7, line 64-column 8,

line 7), in which supercritical fluids such as supercritical carbon dioxide [as in claim 4] and organic solvents and diluents such as the ketone solvent acetone [as in claim 5] are employed (see especially column 6, lines 12-19). Now added, is the Kumar teaching that solvent extraction of marigold oleoresin with ketonic solvents results in product with higher desirable fatty acid ester content (column 4, lines 50-63 and column 5, lines 4-54). It would have been obvious to one of ordinary skill in the art to have modified the processes of Madhavi et al, by substituting or supplementing the solvent extraction steps with a solvent extraction step employing an organic ketone-type solvent such as acetone { as in instant claim 19}, as taught by Kanel et al and Kumar, since the combination of supercritical fluids and the class of solvents including at least acetone are shown to enhance phase transfer and complete recovery of the desired solute(s) into the extraction solvent phase, since ketone type solvent extraction results in product with higher lutein fatty acid ester content and since acetone-type ketone and propanol solvents are interchangeably used in processes combining organic solvent extraction and supercritical solvent extraction, to obtain plant oil resin products such as carotenoids.

For claims 2 and 8-13, high lutein content of as much as 46 % are taught by Kanel et al at Table 1 and at least 50% by Madhavi et al at column 3, lines 62-65. Also, Madhavi et al disclose the solute/solvent mixture to have a quite low viscosity (see column 3, lines 14-16 "...free flowing solution" . Also, see column 3, lines 9-11 concerning deriving of a product containing at least about 20% lutein esters, or higher depending upon total organic solvent employed and time of precipitation .

For claim 17, additional carrier fluids and diluents are taught by Kanel at column 4, lines 3-7 and column 6, lines 12-23.

The pressures and temperatures of claims 18,20 and 21, for the supercritical carbon dioxide are taught by Kanel at column 4, lines 62-column 5, line 2.

Claims (23-26)/15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madhavi et al patent 6,380,442 in view of Kanel et al of record, Rao et al PGPUBS Document US2004/0267033 and Kumar patent 6,737,535 as applied to claims 15, 17-22/15 and 27/15 and further in view of Sakato patent 5,288,550.

For claims 22-26, Kumar discloses marigold oleoresin product which has been purified by solvent extraction with a ketone or other solvent and by filtration techniques, contains a high level of lutein fatty acid ester content and may be in the form of a soft gelatin capsule and thus have a low viscosity (column 4, lines 50-63, column 5, lines 26-48 and column 5, line 65-column 6, line 2). The lutein content well exceeds the claimed 20 or 30 percent recited in claims 22 and 23 when purified (See Examples) and the disclosed conversion into soft gelatin capsule form inherently lowers the viscosity to below the claimed values.

The claims may optionally be deemed to also differ in requiring the purified product to have a specific lowered viscosity. However, Sakato teaches that when pharmaceutical or health/vitamin supplement is dissolved in a hydrophilic solvent, such as acetone or other ketones and then enclosed in a soft gelatin capsule, the viscosity is lowered dramatically (especially column 1, lines 14-21, column 2, lines 26-42 and 57-68

and Table 3 of column 3). It would have been obvious to one of ordinary skill in the art to have modified the product of Kumar by lowering its velocity when converted into soft gelatin capsule form, as taught by Sakato, in order to make the product easier to swallow and digest. Particular viscosity values are shown in the Examples of Sakato.

ALLOWABLE SUBJECT MATTER

Independent claim 16 and thus all claims dependent therefrom are now deemed to distinguish in view of recitation in claim 16 of the process of producing purified marigold oleoresin comprising 1st dissolving in a ketone solvent followed by cooling and precipitating and concentration then subjecting the concentrate to a supercritical fluid extraction. All of the prior art of record only teaches using first a supercritical fluid extraction step followed by a later organic or ketone solvent extraction step.

Applicant's arguments filed on June 7, 2006 have been fully considered but they are not persuasive. The shortcomings of Madhavi have generally been overcome by the newly added and applied teaching Rao et al, Kumar and Sakato references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

June 23, 2006

JOSEPH DRODGE
PRIMARY EXAMINER